

Claims

What is claimed is:

1. A method for preventing leakage into a perigraft space between an endovascular graft that has been implanted in the lumen of a blood vessel of a human or veterinary patient and an adjacent portion of the blood vessel wall, said method comprising the steps of:

(A) providing an expansile polymeric material that i) is initially in a non-expanded state wherein a quantity of the polymeric material occupies a first volume and b) expands to an expanded state wherein said quantity of the polymeric material occupies a second volume larger than the first volume and absorbs blood;

(B) inserting a cannula into a perigraft space between the endovascular graft and the blood vessel wall;

(C) introducing the expansile polymeric material, while in its non-expanded state, through the cannula and into the perigraft space;

(D) allowing the polymeric material to expand to its expanded state within the perigraft space, thereby substantially filling the perigraft space.

2. A method according to Claim 1 wherein i) the adjacent portion of the blood vessel wall is aneurysmic; ii) the endovascular graft is implanted within the blood vessel such that it extends through the aneurysmic portion of the blood vessel and defines a perigraft space between the graft and the aneurysmic wall of the blood vessel; and, iii) the expansile polymeric material is introduced into the perigraft space where it expands to substantially fill the perigraft space with expanded polymeric material.

3. A method according to Claim 2 wherein the quantity of expansile polymeric material that is introduced in Step C is predetermined to substantially fill the space within the aneurysm and outside of the endovascular graft after the polymeric material has been allowed to expand in Step D.

- 1 4. A method according to Claim 1 wherein the expansile polymeric material is
2 radiopaque.
- 1 5. A method according to Claim 4 wherein the expansile polymeric material is rendered
2 radiopaque by the incorporation of radiopaque monomers.
- 1 6. A method according to Claim 1 wherein the polymeric material expands to its
2 expanded state when the pH of its environment is a physiological pH of about 7.4.
- 1 7. A method according to Claim 1 wherein the polymeric material is in the form of
2 pellets when introduced through the cannula.
- 1 8. A method according to Claim 1 wherein the polymeric material is in the form of an
2 elongate filament or tube when delivered to the implantation site.
- 1 9. A method according to Claim 1 wherein the polymeric material is in the form of
2 particles when delivered to the implantation site.
- 1 10. A method according to Claim 1 wherein the polymeric material is delivered to the
2 implantation site through a catheter.
- 1 11. A method according to Claim 10 wherein the catheter is a microcatheter.
- 1 12. A method according to Claim 11 wherein the microcatheter has a lumen of 0.005-
2 0.050 inch diameter, through which the polymeric material is delivered.
- 1 13. A method according to Claim 10 wherein the polymeric material is mixed with a liquid
2 carrier and the liquid carrier/polymeric material mixture is then injected through a lumen of
3 the catheter.

1 14. A method according to Claim 10 wherein the polymeric material is initially attached
2 to a detachable delivery member, the delivery member with the attached polymeric material
3 is advanced transluminally to the implantation site and, thereafter, the polymeric material
4 is detached from the delivery member such that the polymeric material remains implanted
5 in the implantation site after the delivery member has been withdrawn and removed.

1 15. A method according to Claim 2 wherein the polymeric material expands more rapidly
2 as the pH of its environment increases.

1 16. A method according to Claim 1 wherein the polymeric material is a hydrogel.

1 17. A method according to Claim 1 wherein the polymeric material is porous.

1 18. A method according to Claim 17 wherein the porous polymeric material, when
2 substantially fully expanded, has pores of about 50-1000 microns in diameter.

1 19. A method according to Claim 17 wherein the porosity of the polymeric material, when
2 substantially fully expanded, is at least about 50%.

1 20. A method according to Claim 17 wherein the porosity of the polymeric material, when
2 substantially fully expanded, is between about 50% and about 95%.

1 21. A method according to Claim 1 wherein the graft is implanted prior to performance
2 of Step B.

1 22. A method according to Claim 21 wherein Step B further comprises:
2 causing the distal end of the cannula to enter the perigraft space by penetrating
3 through a portion of the graft.

1 23. A method according to Claim 21 wherein Step B further comprises:

1 causing the distal end of the cannula to enter the perigraft space by advancing
2 through tissue of the patient's body, through the wall of the blood vessel adjacent to the
3 graft and into the perigraft space.

1 24. A method according to Claim 23 wherein Step B further comprises:
2 passing a needle through tissues of the patient's body and through the wall of the
3 blood vessel adjacent to the perigraft space; and,
4 advancing the cannula through the needle such that the distal end of the cannula
5 enters the perigraft space.

1 25. A method according to Claim 1 wherein the cannula is a flexible catheter.

1 26. A method according to Claim 1 wherein the cannula is a metal tube.

1 27. A method according to Claim 1 wherein the cannula is a plastic tube.

1 28 A method according to Claim 1 wherein the method is performed after an endoleak
2 has been detected as a means of treating the endoleak.

1 29. A method according to Claim 1 wherein the method is performed before an endoleak
2 has been detected as a means for preventing an endoleak from occurring.

1 30. A method according to Claim 1 wherein Step B comprises:
2 advancing a catheter to a first position within the patient's vasculature; and,
3 advancing the cannula through the catheter to a second position wherein the distal
4 end of the cannula is within the perigraft space.

1 31. A method for preventing leakage into a perigraft space between an endovascular
2 graft and an adjacent blood vessel wall in a human or veterinary patient, said method
3 comprising the steps of:

4 (A) positioning a cannula that has a distal portion within the blood vessel such that
5 the distal portion of the cannula is within the location where the endovascular graft is to be
6 implanted;

7 (B) Implanting the endovascular graft at said location such that the distal portion
8 of the cannula is captured in a perigraft space between the endovascular graft and the wall
9 of the blood vessel;

10 (C) providing an expansile polymeric material that a) is initially in a non-expanded
11 state wherein a quantity of the polymeric material it occupies a first volume and b) expands
12 to an expanded state wherein said quantity of the polymeric material occupies a second
13 volume larger than the first volume;

14 (D) introducing the expansile polymeric material, while in its non-expanded state,
15 through the cannula and into the perigraft space;

16 (E) allowing the polymeric material to expand to its expanded stated within the
17 perigraft space, thereby substantially filling the perigraft space; and,

18 (F) removing the cannula.

1 32. A method according to Claim 31 wherein i) the adjacent portion of the blood vessel
2 wall is aneurysmic; ii) the endovascular graft is implanted within the blood vessel such that
3 it extends through the aneurysmic portion of the blood vessel wall and defines a perigraft
4 space between the graft and the aneurysmic wall of the blood vessel; and, iii) the expansile
5 polymeric material is introduced into the perigraft space where it expands to substantially
6 fill the perigraft space with expanded polymeric material.

1 33. A method according to Claim 2 wherein the quantity of expansile polymeric material
2 that is introduced in Step D is predetermined to substantially fill the space between within
3 the aneurysm and outside of the endovascular graft after the polymeric material has been
4 allowed to expand in Step E.

1 34. A method according to Claim 31 wherein the expansile polymeric material is
2 radiopaque.

1 35. A method according to Claim 34 wherein the expansile polymeric material is
2 rendered radiopaque by the incorporation of radiopaque monomers.

3 36. A method according to Claim 31 wherein the polymeric material expands to its
4 expanded state when the pH of its environment is a physiological pH of about 7.4.

1 37. A method according to Claim 31 wherein the polymeric material is in the form of
2 pellets when introduced through the cannula.

1 38. A method according to Claim 31 wherein the polymeric material is in the form of an
2 elongate filament or tube when delivered to the implantation site.

1 39. A method according to Claim 31 wherein the polymeric material is in the form of
2 particles when delivered to the implantation site.

1 40. A method according to Claim 31 wherein the cannula through which the polymeric
2 material is delivered comprises a catheter.

1 41. A method according to Claim 40 wherein the catheter is a microcatheter.

1 42. A method according to Claim 41 wherein the microcatheter has a lumen of 0.005-
2 0.050 inch diameter, through which the polymeric material is delivered.

1 43. A method according to Claim 40 wherein the polymeric material is mixed with a liquid
2 carrier and the liquid carrier/polymeric material mixture is then injected through a lumen of
3 the catheter.

1 44. A method according to Claim 40 wherein the polymeric material is initially attached
2 to a detachable delivery member, the delivery member with the attached polymeric material
3 is advanced transluminally to the implantation site and, thereafter, the polymeric material

4 is detached from the delivery member such that the polymeric material remains implanted
5 in the implantation site after the delivery member has been withdrawn and removed.

1 45. A method according to Claim 42 wherein the polymeric material expands more
2 rapidly as the pH of its environment increases.

1 46. A method according to Claim 41 wherein the polymeric material is a hydrogel.

1 47. A method according to Claim 41 wherein the polymeric material is porous when in
2 its expanded state.

1 48. A method according to Claim 47 wherein the porous polymeric material, when
2 substantially fully expanded, has pores of about 50 to about 300 microns in diameter.

1 49. A method according to Claim 47 wherein the porosity of the polymeric material, when
2 substantially fully expanded, is at least about 10%.

1 50. A method according to Claim 47 wherein the porosity of the polymeric material, when
2 substantially fully expanded, is between about 20% and about 95%.

1 51. A method according to Claim 31 wherein Step A further comprises:
2 advancing a catheter to a position near the location where the endovascular graft is
3 to be implanted; and,
4 advancing the cannula through the catheter to a position where the distal portion of
5 the cannula is within the location where the endovascular graft is to be implanted.

1 52. A method according to Claim 51 wherein the cannula is sufficiently strong that the
2 lumen of the cannula does not become substantially collapsed when the distal portion of
3 the cannula is captured between the endovascular graft and the wall of the blood vessel;

1 53. A system for preventing or treating endoleaks in a human or veterinary patients in
2 whom an endovascular graft having a wall has been implanted, said system comprising:
3 an elongate catheter having an outlet port and a lumen that extends longitudinally
4 through the catheter and through the outlet port, said catheter being insertable into the
5 patient's vasculature and positionable within the implanted endovascular graft such that the
6 outlet port is directed at the wall of the endovascular graft;
7 a cannula that is advanceable through the lumen of the catheter, out of the outlet
8 port, through the wall of the endovascular graft and into the perigraft space;
9 a stabilization member formed on the catheter to stabilize the catheter in the area of
10 the outlet port such that, as the cannula is advanced through the wall of the endovascular
11 graft, the catheter will not recoil in a direction opposite the direction in which the cannula is
12 being advanced; and,
13 a quantity of an expansile polymeric material that i) is initially in a non-expanded state
14 wherein a quantity of the polymeric material occupies a first volume and b) expands to an
15 expanded state wherein said quantity of the polymeric material occupies a second volume
16 larger than the first volume and absorbs blood, said polymeric material being injectable
17 through the cannula after the cannula has been advanced into the perigraft space and
18 thereafter expanding to its expanded state within the perigraft space.

1 54. A system according to Claim 53 wherein the catheter is a flexible catheter having a
2 distal end that is deflectable, wherein the operator may volitionally deflect the catheter's
3 distal end to cause the so as to direct the catheter's outlet port toward the wall of the
4 endovascular graft prior to advancement of the cannula.

1 55. A system according to Claim 53 wherein the outlet port is located in the side of the
2 catheter.

1 56. A system according to Claim 53 wherein the endovascular graft has a substantially
2 continuous wall and the cannula has a distal end that is sufficiently sharp to penetrate
3 through the wall of the endovascular graft.

- 1 56. A system according to Claim 53 wherein the cannula is a microcatheter.
- 1 57. A system according to Claim 53 wherein the stabilizing member is a balloon.
- 1 58. A system according to Claim 53 wherein the balloon, when inflated, pushes the
2 portion of the catheter wherein the outlet port is formed against the wall of the endovascular
3 graft such that the outlet port is directed into the wall of the endovascular graft.
- 1 59. A system according to Claim 53 wherein the expansile polymeric material is rendered
2 radiopaque by the incorporation of radiopaque monomers.
- 1 60. A system according to Claim 53 wherein the polymeric material expands to its
2 expanded state when the pH of its environment is a physiological pH of about 7.4.
- 1 61. A system according to Claim 53 wherein the polymeric material is in the form of
2 pellets when delivered through the cannula.
- 1 62. A system according to Claim 53 wherein the polymeric material is in the form of an
2 elongate filament or tube when delivered through the cannula.
- 1 63. A system according to Claim 53 wherein the polymeric material is in the form of
2 particles when delivered through the cannula.
- 1 64. A system according to Claim 53 wherein the expansile polymeric material is
2 radiopaque.
- 1 65. A system according to Claim 53 wherein the cannula has a lumen of 0.005-0.050
2 inch diameter, through which the polymeric material is delivered.
- 1 66. A system according to Claim 53 wherein the polymeric material is mixed with a liquid
2 carrier.

1 67. A system according to Claim 53 wherein the polymeric material is initially attached
2 to a detachable delivery member, the delivery member with the attached polymeric material
3 is advanced through the cannula and into the perigraft space and, thereafter, the polymeric
4 material is detached from the delivery member such that the polymeric material remains
5 implanted in the implantation site after the delivery member is then withdrawn proximally
6 through the cannula.

1 68. A system according to Claim 53 wherein the polymeric material expands more rapidly
2 as the pH of its environment increases.

1 69. A system according to Claim 53 wherein the polymeric material is a hydrogel.

1 70. A system according to Claim 53 wherein the polymeric material is porous when in its
2 expanded state.

1 71. A system according to Claim 53 wherein the porous polymeric material, when
2 substantially fully expanded, has pores of about 50 to about 300 microns in diameter.

1 72. A system according to Claim 53 wherein the porosity of the polymeric material, when
2 substantially fully expanded, is at least about 10%.

1 73. A system according to Claim 53 wherein the porosity of the polymeric material, when
2 substantially fully expanded, is between about 20% and about 95%.